

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

MALLINCKRODT PHARMACEUTICALS	)	
IRELAND LIMITED and	)	
MALLINCKRODT	)	
HOSPITAL PRODUCTS IP UNLIMITED	)	
COMPANY	)	
	)	
Plaintiffs,	)	C.A. No. 22-01648 (RGA)
	)	
v.	)	
	)	
AIRGAS THERAPEUTICS LLC, AIRGAS	)	
USA LLC, and AIR LIQUIDE S.A.,	)	
	)	
Defendants.	)	
	)	

**PROTECTIVE ORDER**

WHEREAS the Parties (as defined herein) agree that the nature of this case will require the Parties to seek and produce documents and information, and elicit deposition testimony, the disclosure of which poses a substantial risk of harm to the Producing Party's (as defined herein) legitimate proprietary interests;

WHEREAS the Parties agree that a protective order is necessary to minimize the harm flowing from the disclosure of sensitive information; and

WHEREAS the Parties agree to the terms of this Order to protect their confidential documents, things and information;

IT IS HEREBY ORDERED THAT the Parties and any non-party subject to discovery in this action are bound by the terms of this Protective Order governing the production of Confidential Information (as defined herein) in this action.

1. **Scope of Protective Order:** This Protective Order applies to all Discovery Materials (as defined herein) produced by a Producing Party in connection with this action. In addition, this Protective Order allows for the filing of documents with the Court under seal, subject to any applicable Local Court Rule or CM/ECF procedure, if such documents contain Confidential Information. This Protective Order shall apply regardless of whether such information was produced prior to or after entry of this Protective Order.

2. **Definitions:**

- (a) The term “Confidential Information” means any information, whether oral or in documentary or other tangible form, so designated by any Producing Party that it reasonably and in good faith believes is of the type protectable under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure or is required to be kept Confidential by law or by agreement with a third party or otherwise. Any summary, compilation, notes, memoranda, analysis or copy containing Confidential Information and any electronic image or database containing Confidential Information shall be considered Confidential Information to the same extent as the material or information from which such summary, compilation, notes, copy, memoranda, analysis, electronic image, or database is derived.

Examples of the types of information that may be requested in discovery and designated as “Confidential Information” if produced include, but are not limited to:

- (i) The names, or other information tending to reveal the identities, of a Party’s suppliers, present or prospective customers, or distributors or the personal information of a Party’s employees;
- (ii) Information relating to pending patent applications;
- (iii) Financial information of a Party, including, but not limited to, identifying the number of products sold, total dollar value of products sold, and profit margins for products, both forecasted and actual;
- (iv) Information constituting product specifications, formulations and/or regarding the manufacture of the Party’s products;
- (v) Technical notebooks and technical reports of a Party, including product and manufacturing specifications, schematic diagrams, technical reference manuals, operations manuals, or other similar information;
- (vi) Confidential marketing plans, market research and business strategy, including research regarding competitors;
- (vii) Information the Producing Party believes is a proprietary trade secret;
- (viii) Personal information and/or identities of physicians and patients;
- (ix) All information relating to a Party’s research and development efforts leading to the creation of its INOMAX® (Nitric Oxide)

inhalation product, its NDA and any correspondence with the FDA as well as any 510K; and

- (x) All Abbreviated New Drug Applications (including any supplements, amendments or other correspondence with the FDA), confidential portions of New Drug Applications, or Drug Master Files as well as any 510K.
- (b) The term “disclose” means to show, give, make available or communicate, in any fashion, to any Person (as defined herein), any information, document, information concerning the content of any document, or any portion of the information contained in any document, furnished by any Party or non-party in this action.
- (c) The term “Discovery Material” means any document or thing, and includes, without limitation, any writings, video or audio media, computer-generated or recorded information in any form, materials, oral or written testimony, interrogatories, answers to interrogatories, requests for admission, responses to requests for admission, document requests, responses to document requests, deposition testimony, deposition transcripts and exhibits, and other responses to requests for information or any tangible thing, produced by a Party or non-party in this action.
- (d) The term “Outside Counsel” means attorneys from the following law firms: Sterne Kessler Goldstein & Fox PLLC, Richards Layton & Finger P.A., Buchanan Ingersoll & Rooney PC, Foley Hoag LLP, Farnan LLP, Phillips, McLaughlin & Hall, P.A. including associated personnel necessary to assist outside counsel in this action, such as legal assistants, paralegals, analysts, secretarial, stenographic, information technology and clerical employees actually assisting such counsel; outside litigation vendors; translation service vendors; computer services; mock jurors and trial/jury consultants, their employees, and independent contractors hired to assist them, other than those persons described in Paragraph 2(h)(4) below.
- (e) The terms “Parties” or “Party” mean the following plaintiffs and/or defendants in this civil action: Mallinckrodt Pharmaceuticals Ireland Limited and Mallinckrodt Hospital Products IP Unlimited Company, Airgas Therapeutics, Airgas USA LLC. In the event that the Court denies Air Liquide S.A.’s motion to dismiss pursuant to Rule 12(b)(2) and Rule 12(b)(6), the terms “Parties” or “Party” shall include Air Liquide S.A. Unless and until the Court denies ALSA’s motion to dismiss, ALSA will be treated as a non-party.
- (f) The term “Person” means any natural person or any business, legal or governmental entity or association.

- (g) The term “Producing Party” means any Party, Person or non-party who produces any information, whether oral or in documentary or other tangible form.
- (h) The term “Qualified Person” means (1) Outside Counsel; (2) no more than two in-house counsel (collectively “in-house counsel”) who agree to be bound by the terms of the Protective Order by signing the attached Undertaking, and paralegals or secretaries who support such in-house counsel; (3) current or former employees of any Party who are authors, addressees, or who were copied on correspondence containing the relevant documents, or who otherwise previously had access to the relevant documents; (4) outside independent experts, consultants, and professional vendors (e.g., trial vendors, graphics vendors, etc.) of the Parties who are assisting Outside Counsel in this action and any necessary assistants and stenographic and clerical employees under their direct supervision and employed by them or their employer or organization, provided that any applicable requirements of Paragraph 7 below are satisfied; (5) the Court and Court personnel, including stenographic reporters; (6) court reporters and videographers taking testimony involving Confidential information; (7) persons who have been retained by a Party to provide translation or interpretation from one language to another; (8) any person to whom the Producing Party agrees in writing; and (9) any person to the extent required by Court order .
- (i) The term “Receiving Party” means any Person to whom Confidential Information is disclosed in this action.
- (j) Any other term not defined herein shall carry its ordinary meaning.

**3. Designation of Confidential Information:**

- (a) Discovery Material, or any relevant portion of any letter, brief, motion, affidavit, discovery response, discovery request or other pleading, may be designated by any Producing Party as “Confidential,” provided the material meets the definition of “Confidential Information” herein. Moreover, a Party may designate Discovery Material produced by non-parties that contain that Party’s Confidential Information as “Confidential.”

A Producing Party may designate as Confidential any of its Discovery Material that may be protected under Fed. R. Civ. P. 26(c) and for which a good faith claim of a need for protection from disclosure can be made under applicable law. The designations shall be made or supervised by an attorney. Any information supplied in documentary or other tangible form may be designated by the Producing Party, or other Person claiming that the information is Confidential Information, by placing or affixing on each page of such Document, or on the face of such thing, the legend “CONFIDENTIAL- PURSUANT TO PROTECTIVE ORDER”.

Information, documents, articles and things previously produced under protective orders in other cases that bear appropriate confidentiality markings from such other cases need not be stamped again; such material stamped with any confidentiality marking and produced in this litigation will be treated as Confidential Information, in accordance with the terms of this Protective Order.

4. **Confidential Testimony:** Testimony obtained from a deposition or hearing may be designated Confidential, when appropriate, either on the record at the deposition or hearing or by letter within thirty (30) days after receipt of the final (i.e., not “draft” or “rough”) transcript. Subject to any requirements of the Court, the reporter for any deposition or hearing shall affix a mark of “CONFIDENTIAL-PURSUANT TO PROTECTIVE ORDER” to pages that contain testimony designated as such. All such transcripts shall be treated as Confidential until designated otherwise or until the time to so designate has expired as set forth in this provision, whichever is later. If designations are not made on the record or within thirty (30) days after receipt of the final transcript, the transcript shall be considered not to contain Confidential Information.

5. **Publicly Available Material:** Discovery Material that has been provided to any government agency that is available to the public, either by the Freedom of Information Act or any other federal or state law, and Discovery Material which is otherwise available to the public from any source, should not be designated as “CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER”. If a Party receives material designated “CONFIDENTIAL-PURSUANT TO PROTECTIVE ORDER” that the Party believes falls under this Paragraph, the Party may challenge the designation and request relief from the Court, after conferring in good faith with Outside Counsel for the Producing Party. If the Party seeks relief from the Court, until the Court rules on the requested relief, the Discovery Material shall be treated as “Confidential Information”. The Party or Person claiming that the material is “Confidential Information” bears the burden of establishing the confidentiality of the so- designated materials.

6. **Nondisclosure of Confidential Information:** Except with the prior written consent of the Party or Person originally designating Discovery Material as “CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER,” or as provided in this Protective Order, no Confidential Information may be disclosed to any Party or Person, other than a Qualified Person as set forth in Paragraph 2(h) above.

7. **Disclosure of Confidential Information to Experts, Consultants, In-House Counsel, and Outside Counsel:**

Any information designated as “Confidential Information” shall be maintained in confidence by any Receiving Party. Confidential Information may be disclosed only to Qualified Persons as set forth in Paragraph 2(h) above. Subject to the below restrictions, Confidential Information may be disclosed to Qualified Persons in categories (1), (2), and (4) of Paragraph 2(h) above.

- (a) Independent Experts and Consultants. The following applies for each independent expert and consultant described in Paragraph 2(h)(4) above to

whom Confidential Information is to be given, shown, disclosed, made available or communicated in any way:

- (i) Prior to any disclosure of Confidential Information to such independent expert or consultant, such expert or consultant shall first read this Protective Order and sign the Undertaking attached hereto.
  - (ii) At least five (5) business days prior to the Receiving Party giving, showing, disclosing, making available or communicating Confidential Information to any expert or consultant, the Receiving Party shall deliver (by electronic mail) to all other Parties a copy of the signed Undertaking and a resume, curriculum vitae, a list of all other cases in which, during the previous four (4) years, the expert testified at trial or by deposition.
  - (iii) If a Party has a good faith basis for believing it would be harmed by the proposed disclosure, the Party shall be entitled to object to such disclosure within five (5) business days after service of the information called for in Paragraph 7(a)(ii). Objections must be in writing and state with particularity the basis for the objection.
  - (iv) In the event of such an objection to disclosure of Confidential Information, the Parties shall meet and confer within three (3) business days to attempt to resolve the concerns giving rise to the objection. If the parties are unable to reach an agreement regarding such disclosure, the Party objecting to disclosure may, within five (5) business days of the meet and confer, request that the Court issue an order barring such disclosure. The objecting Party shall have the burden of showing why that person should not have access to Confidential Information. Pending resolution of any such motion or application, no disclosure of Confidential Information shall be made to the objected-to person. The filing and pendency of such motion shall not limit, delay or defer any disclosures of Confidential Information to persons as to whom no such objection has been made.
- (b) Designated In-House Counsel. The following applies for each in-house counsel designated under the terms of this Order:
- (i) Absent written consent from the Producing Party, for the duration of one year after the conclusion of the litigation including appeals, designated in-house counsel shall not, directly or indirectly, draft, edit, or amend claims or claim language in any U.S. patent or U.S. patent application during any pre- or post-grant patent office proceeding directly relating to the opposing party's nitric oxide product and/or nitric oxide delivery system. Notwithstanding the

foregoing, nothing herein shall preclude designated in-house counsel from working on and participating in, directly or indirectly, (i) all aspects of any *inter partes* review, post-grant review, or re-issue or re-examination proceeding at the U.S. Patent and Trademark Office or the Patent Trial and Appeal Board of any of the asserted patents or related patent applications, except for drafting, editing, or amending claims or claim language directly relating to the opposing party's nitric oxide product and/or nitric oxide delivery system, and (ii) all aspects of any pre- or post-grant opposition proceedings or invalidation request proceedings before a foreign patent office or court for any asserted patent or related patent application, except for drafting, editing, or amending claims or claim language directly relating to the opposing party's nitric oxide product and/or nitric oxide delivery system. To avoid any misunderstanding, and consistent with the scope of the foregoing terms, nothing herein shall preclude such individuals from engaging in supervisory roles in patent prosecution that do not involve drafting, editing, amending, or providing instruction with respect to the drafting, editing, or amending of claims directly relating to the opposing party's nitric oxide product and/or nitric oxide delivery system, or being involved in proceedings or litigations relating to patent term extension under 35 U.S.C. § 156 *et seq.* or patent term adjustment under 35 U.S.C. § 154 *et seq.* for any asserted patent or related patent application.

- (ii) Prior to any Confidential Information being provided to any in-house counsel identified above, each in-house counsel shall read this Protective Order and sign the Undertaking for In-House Counsel attached hereto. The Party seeking disclosure of the Information shall deliver (by electronic mail) a copy of the executed Undertaking to each Party.
- (iii) In the event that any of the in-house counsel identified above no longer can serve as a designated in-house counsel in this action, the designating Party may select a replacement in-house counsel to view Confidential Information of the Producing Party. The new in-house counsel shall execute an Undertaking as required herein and shall otherwise comply with all terms of this Protective Order. The Party seeking disclosure to a replacement in-house counsel shall deliver (by electronic mail) a copy of the executed Undertaking to each Party. If a Party has a good faith basis for believing it would be harmed by the proposed disclosure, the Party shall be entitled to object to such disclosure within ten (10) business days after service of the Undertaking. Objections must be in writing and state with particularity the basis for the objection.



In the event of such an objection to disclosure of Confidential Information to in-house counsel, the Parties shall meet and confer within five (5) business days to attempt to resolve the concerns giving rise to the objection. If the parties are unable to reach an agreement regarding such disclosure, the Party objecting to disclosure may, within five (5) business days of the meet and confer, request that the Court issue an order barring such disclosure. The objecting Party shall have the burden of showing why that person should not have access to Confidential Information. Pending resolution of any such motion or application, no disclosure of Confidential or Information shall be made to that person. The filing and pendency of such motion shall not limit, delay or defer any disclosures of Confidential Information to persons as to whom no such objection has been made.

(c) Outside Counsel.

- (i) Absent written consent from the Producing Party, for the duration of one year after the conclusion of the litigation including appeals, Outside Counsel who has access to or reviews Confidential Information shall not draft, edit, or amend claims or claim language in any U.S. patent or U.S. patent application during any pre- or post-grant patent office proceeding directly relating to the opposing party's nitric oxide product and/or nitric oxide delivery system. Notwithstanding the foregoing, nothing herein shall preclude Outside Counsel from working on and participating in, directly or indirectly, (i) all aspects of any *inter partes* review, post-grant review, or re-issue or re-examination proceeding at the U.S. Patent and Trademark Office or the Patent Trial and Appeal Board of any of the asserted patents or related patent applications, except for drafting, editing, or amending claims or claim language directly relating to the opposing party's nitric oxide product and/or nitric oxide delivery system, and (ii) all aspects of any pre- or post-grant opposition proceedings or invalidation request proceedings before a foreign patent office or court for any asserted patent or related patent application, except for drafting, editing, or amending claims or claim language directly relating to the opposing party's nitric oxide product and/or nitric oxide delivery system. To avoid any misunderstanding, and consistent with the scope of the foregoing terms, nothing herein shall preclude such individuals from engaging in supervisory roles in patent prosecution that do not involve drafting, editing, amending, or providing instruction with respect to the drafting, editing, or amending of claims directly relating to the opposing party's nitric oxide product and/or nitric oxide delivery system, or being involved in proceedings or litigations relating to patent term extension under 35 U.S.C. § 156 *et seq.* or patent term adjustment under 35 U.S.C. § 154 *et seq.* for



any asserted patent or related patent application. Moreover, the foregoing restrictions shall apply only to individuals, and not to the firms or organizations by which they are employed, nor to individuals who received access to Confidential Information solely in their capacity as clerical staff.

**8. Use of Designated Materials:**

- (a) Subject to Paragraph 14 below, Confidential Information shall be used by the Receiving Party solely for the purposes of the above-captioned action only. Confidential Information shall not be used or disclosed in any submission to the United States FDA, United States Pharmacopeia, British Pharmacopeia, European Pharmacopeia or European Medicines Agency.

In addition, subject to Paragraph 15 below, Confidential Information shall not be used to prosecute any patent application.

- (b) Confidential Information may be disclosed by a Receiving Party during a deposition, to the extent that its use is reasonably necessary, at the depositions of the following:
  - (i) The present directors, officers, employees, agents or Rule 30(b)(6) designees of the Producing Party;
  - (ii) An author, addressee, or other person indicated as a lawful recipient of a document containing the information;
  - (iii) A person not within subparagraphs 8(b)(i)-(ii) above who is clearly identified in prior discovery or by the deponent in his or her deposition as an author or recipient of the information (without prior disclosure of the Confidential Information);
  - (iv) An independent advisor, consultant or expert otherwise qualified under this Protective Order to receive such information;
  - (v) Any person for whom prior authorization is obtained from the Producing Party or the Court; or
  - (vi) Individuals who have been identified through discovery (including document production, written discovery or deposition testimony) as having knowledge of the particular Confidential Information, even if the individual is not identified as an actual author or recipient on the face of the document at issue.

Nothing in this section shall preclude counsel from questioning a witness at a deposition about whether the witness falls into 8(b)(i)-(vi).

9. **Inadvertent Productions:**

- (a) In the event any document is produced that the Producing Party later claims is protected by the attorney-client privilege, work-product doctrine, or other privilege or immunity, the Receiving Party shall, as soon as possible but not later than within five (5) business days of receipt of a written request by the Producing Party, return the original to the Producing Party, or at the option of the Receiving Party, destroy the original, and all copies of the same. The Receiving Party shall also destroy or delete all notes, memoranda or other documents that summarize, discuss or quote the document, as well as any copies of the document, or any portion thereof, from any word processing or database electronic medias it maintains. The Receiving Party shall further provide written verification to Outside Counsel for the Producing Party that all such materials have been returned, destroyed, or deleted. Upon receiving notice of inadvertent production, the Receiving Party(ies) shall not make any use of such document or thing or disseminate the same in any way. The unintentional or inadvertent production of privileged, work-product-protected or otherwise immune documents in the course of discovery in this action shall not constitute a waiver of any privilege, work-product-protection or immunity, either as to the produced document or as to any other documents or communications embracing the same or similar subject matter provided that the Producing Party notifies the Receiving Party in writing of such unintentional or inadvertent production promptly (and no later than ten (10) business days) after the Producing Party discovers, or should have discovered, such unintentional or inadvertent production. Return or destruction of a document for which the Producing Party has asserted a claim of privilege, work-product-protection or immunity under this paragraph shall be without prejudice to the Receiving Party's right to seek an order from the Court directing production of the document on the ground that the claimed privilege, work-product-protection or immunity is invalid, inapplicable or waived, provided, however, that any motion or other application for such order shall not rely upon in any manner or assert as a ground the fact or circumstances of the unintentional or inadvertent production, nor shall it disclose the substance of the inadvertently produced material except to the extent that an *in camera* inspection of the materials is requested.
- (b) Unintentional or inadvertent failure to designate any information as "Confidential" pursuant to this Protective Order shall not constitute a waiver of any otherwise valid claim for protection, provided that the Producing Party notifies the Receiving Party in writing of such unintentional or inadvertent failure to designate promptly (and no later than ten (10) business days) after the Producing Party discovers such unintentional or inadvertent failure to designate. In the event of an unintentional or inadvertent failure to designate any information, arrangements shall be made for the return to the Producing Party, or the destruction or deletion of, all copies of the unintentionally or inadvertently

undesignated information and for the substitution, where appropriate, of properly labeled copies. The Parties shall undertake their best efforts to correct any disclosure of such information contrary to re-designation, including retrieving any documents from persons not qualified to receive them under the re-designation and informing such persons that they should not further use or disseminate the information thereon. No demonstration or proof of error, inadvertence, or excusable neglect by the Producing Party shall be required for such re-designation.

- (c) This Protective Order shall not preclude the parties from enforcing their rights under Fed. R. Evid. 502.

10. **Redactions:** Documents and things produced or made available for inspection may be subject to redaction, in good faith by the Producing Party, of information that is subject to the attorney-client privilege or to the work-product immunity. Each such redaction, regardless of size, shall be clearly labeled. All documents redacted based on point (ii) shall be listed on a privilege log stating the basis for such redaction, but only where such document was generated prior to December 30, 2022. This Paragraph shall not be construed as a waiver of any Party's right to seek disclosure of redacted information.

11. **Filing:** All documents - including pleadings, motions and other papers - containing Confidential Information shall be filed with the Court under seal in accordance with the Court's Local Rules and CM/ECF procedures.

12. **Changes to Confidentiality Designations and Requests to Disclose Confidential Information to Non-Parties:** Nothing herein shall be taken as indicating that any document or information designated as Confidential Information is entitled to such treatment. If the Receiving Party desires to disclose Confidential Information to someone other than a Qualified Person as permitted in Paragraphs 6-7 above, or if the Receiving Party disagrees with the confidentiality designation by the Producing Party, then the Receiving Party shall so notify, in writing, Outside Counsel for the Person or Party asserting the confidentiality of the information. Outside Counsel for the Person or Party asserting the confidentiality of the information and the Receiving Party shall first try to resolve such dispute within five (5) business days after receipt of the Receiving Party's notice. If the dispute cannot be resolved, the Receiving Party, upon no fewer than three (3) business days written notice to the Person or Party asserting the confidentiality, may seek a ruling from the Court that the information is improperly designated or that such disclosure should take place because the interest of the Person or Party asserting the confidentiality in limiting the dissemination of the information is outweighed by the need for such disclosure.

13. **Preservation of the Right to Challenge Confidentiality Designation:** No party shall be obligated to challenge the propriety of a confidentiality designation, and a failure to do so shall not preclude a subsequent challenge to the propriety of such designation. This Protective Order shall be without prejudice to the right of any Party or other subscriber to this Protective Order (a) to bring before the Court at any time the question of whether any particular document or information is Confidential Information or whether its use otherwise should be restricted or (b) to present a motion to the Court under Fed. R. Civ. P. 26(c), for a separate protective order as to

any such particular document or information, including restrictions differing from those specified herein.

14. **Subpoena by Other Courts or Agencies:** If Confidential Information in the possession, custody or control of any Receiving Party is sought by subpoena, request for production of documents, interrogatories, or any other form of discovery request or compulsory process, including any form of discovery request or compulsory process of any court, administrative or legislative body or any other person or tribunal purporting to have authority to seek such information by compulsory process or discovery request, including private parties, the Receiving Party to whom the process or discovery request is directed, shall (a) on or before the third business day of receipt thereof, give written notice by hand, email or facsimile of such process or discovery request, together with a copy thereof, to Outside Counsel for the Producing Party; (b) withhold production or disclosure of such Confidential Information until the Producing Party consents in writing to production or the Receiving Party is required by a court order to produce such Confidential Information, so long as the order is not stayed prior to the date set for production or disclosure and, in any event, provided that the Receiving Party provides a copy of such court order to Outside Counsel for the Producing Party prior to disclosure; and (c) otherwise cooperate to the extent necessary to permit the Producing Party to seek to quash or modify such process or discovery request.

15. **Expert Discovery:** In addition to Fed. R. Civ. P. 26(a)(2) and (b)(4), written or oral communications, and notes of communications, between any expert and counsel for a Party, including any attachments or draft documents are outside the scope of permissible Discovery Materials and are not discoverable, unless the expert relies on such information as a basis for their opinion.

16. **Client Consultation:** Nothing in this Protective Order shall prevent or otherwise restrict Outside Counsel or designated in-house counsel from rendering advice to their clients and, in the course thereof, relying generally on examination of Confidential Information; provided, however, that in rendering such advice and otherwise communicating with such clients, Outside Counsel or designated in-house counsel shall not make specific disclosure of any item so designated except as permitted herein.

17. **Modification Permitted:** Nothing in this Protective Order shall prevent any Party or other Person from seeking modification of this Protective Order, from objecting to discovery that it believes to be otherwise improper, from applying to the Court for relief therefrom, or from applying to the Court for further or additional protective orders, or from agreeing among themselves to modify or vacate this Protective Order, subject to the approval of the Court. The Court retains jurisdiction even after termination of this action to enforce this Protective Order and to make such amendments, modifications, deletions and additions to this Protective Order as the Court may from time to time deem appropriate.

18. **Responsibility of Attorneys:** The attorneys of record for each respective party are responsible for employing reasonable measures, consistent with this Protective Order, to control duplication of, access to, and distribution of copies of Confidential Information received by them.

19. **No Waiver:** Review of Confidential Information by Qualified Persons as permitted in Paragraphs 6-7 above in connection with this action shall not waive the confidentiality of the information or objections to production. The inadvertent, unintentional, or *in camera* disclosure of Confidential Information shall not, under any circumstances, be deemed a waiver, in whole or in part, of any Party's claims of confidentiality.

20. **Purpose Is to Facilitate the Exchange of Information:** This Protective Order is entered solely for the purpose of facilitating the exchange of information between the Parties to this action without involving the Court unnecessarily in this process. Nothing in this Protective Order, nor the production of any documents or disclosure of any information pursuant to this Protective Order, shall be deemed to have the effect of (a) an admission or waiver, including waiver under the Federal Rules of Evidence or applicable Local Rules, by any Party or other subscriber to this Protective Order; (b) altering the confidentiality of any such information; or (c) altering any existing obligation of any party or other subscriber, or the absence of such obligation.

21. **Termination of the Litigation:** Within 90 days after the final conclusion of this litigation, including all appeals, all Confidential Information, and all copies of the same, shall be returned to the Producing Party or, at the option of the Receiving Party, destroyed. This includes all notes, memoranda or other documents that summarize, discuss or quote materials produced and designated as Confidential Information, except that, with respect to word processing and electronic back-up media, electronic media or other archival media, the Receiving Party shall destroy or erase such electronic back-up media, electronic media or other archival media to the extent practicable. Outside Counsel for each Party shall be entitled to (but is not obligated to) retain copies of all court filings (including exhibits), any attorney work-product, any transcripts of depositions (including exhibits), hearings or trial testimony in this action, written discovery and discovery responses, and documents included on trial exhibit lists that contain or refer to information designated as Confidential Information provided that all such documents shall remain subject to this Protective Order. Outside Counsel of record shall make certification of compliance herewith and shall deliver the same to Outside Counsel for the party that produced the documents not more than 90 days after conclusion of this litigation, including all appeals.

22. **No Limitations on Party's Use of its Own Information:** Except as specifically noted herein, this Protective Order shall not limit a Producing Party's use of its own Confidential Information.

23. **Third Parties:** This Protective Order applies to the parties to this case, and in the event additional parties are added, join, or are joined in this Action, they shall file with the Court its agreement to be fully bound by this Protective Order. If a third party provides Discovery Materials to any Party, such third party may adopt the terms of this Protective Order with regard to the production of Confidentiality Agreement and Protective Order. Under such circumstances, the third party shall have the same rights and obligations under this Protective Order as held by the Parties to this litigation.

24. **Information Not Covered by this Protective Order:** The restrictions set forth in this Protective Order will not apply to Confidential Information that is in the possession of or otherwise known to the Receiving Party or the public before the date of its transmission to the

Receiving Party, or which comes into the lawful possession of or becomes known to the Receiving Party or comes into the possession of or otherwise becomes known to the public after the date of its transmission to the Receiving Party, provided that, as shown in written records, such information does not become publicly known by any act or omissions of the Receiving Party which would be in violation of this Protective Order.

25. **Survival:** This Protective Order shall survive and remain in full force and effect after termination of this action. Neither the termination of this lawsuit nor the termination of employment of any person with access to any Confidential Information shall relieve such person from the obligation of maintaining the confidentiality of such information.

26. **Pending Entry by the Court:** Until a protective order has been entered in this action, the parties agree that the confidentiality provisions of Local Rule 26.2 apply.

27. **Other Proceedings:** By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's information designated as confidential pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

By: /s/ Sara M. Metzler

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*Attorneys for Defendants, Airgas Therapeutics,  
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**SO ORDERED**, this 14 day of September 2023.

/s/ Richard G. Andrews

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UNITED STATES DISTRICT JUDGE

**UNDERTAKING AND ACKNOWLEDGEMENT OF  
PROTECTIVE ORDER AND CONFIDENTIALITY STIPULATION**

I, \_\_\_\_\_ hereby attest as follows:

1. I understand that CONFIDENTIAL material may be disclosed to me under the terms of the Protective Order attached to this Undertaking and Acknowledgement. I have a copy of and have read the Order, and I agree to comply with and be bound by its terms. I also agree to be subject to the jurisdiction of this Court for the purpose of enforcing this Order and this agreement.

2. I agree that I will not disclose to anyone else the CONFIDENTIAL material disclosed to me, nor discuss or describe the substance or content of such material, except as provided in the Order, and that I will use such material only for the purposes of this litigation.

3. I agree that I will not keep any CONFIDENTIAL or copies of any such material (including notes or other memoranda or writings containing or relating to such material) except to the extent permitted by the Order, and, upon request, will destroy or return such material to the attorneys who disclosed such material to me.

Dated: \_\_\_\_\_

\_\_\_\_\_  
Signature